for the safe use of 1-bromo-3-chloro-5,5-dimethylhydantoin (CAS Reg. No. 16079-88-2) as a slimicide in the manufacture of paper and paperboard intended to contact food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4 (b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before July 14, 1994, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: June 2, 1994.

Janice F. Oliver,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 94-14371 Filed 6-13-94; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 93E-0099]

Determination of Regulatory Review Period for Purposes of Patent Extension; Mycobutin™; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of April 15, 1994 (59 FR 18133), that announced its determination of the regulatory review period for purposes of patent extension for Mycobutin™ (rifabutin). The document was published with some mathematical errors. The document incorrectly stated, "FDA has determined that the applicable regulatory review period for Mycobutin™ is 2,831 days. Of this time, 2,124 days occurred during the testing phase of the regulatory review period, while 707 days occurred during the approval phase." It should have stated, "FDA has determined that the applicable regulatory review period for Mycobutin™ is 2,469 days. Of this time, 2,127 days occurred during the testing phase of the regulatory review period, while 342 days occurred during the approval phase." This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

In FR Doc. 94-9099, appearing on page 18133 in the Federal Register of April 15, 1994, the following corrections are made: On page 18134, in the first column, in the second complete paragraph, in line 3, "2,831" is corrected to read "2,469"; in line 4, "2,124" is corrected to read "2,127"; and in line 6, "707" is corrected to read "342".

Dated: June 8, 1994.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 94-14446 Filed 6-13-94; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 94M-0180]

Sigmedics, Inc.; Premarket Approval of Parastep® I System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Sigmedics, Inc., Northfield, IL, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of the Parastep® I System. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 20, 1994, of the approval of the application.

DATES: Petitions for administrative review by July 14, 1994.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Marie A. Schroeder, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-594-1296.

SUPPLEMENTARY INFORMATION: On September 30, 1992, Sigmedics, Inc., One Northfield Plaza, suite 410, Northfield, IL 60093-3016, submitted to CDRH, an application for premarket approval of the Parastep® I System. The device is a noninvasive functional neuromuscular stimulator for ambulation and is indicated for enabling appropriately selected skeletally mature spinal cord injured patients (levels C6-T12) to stand and to attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury.

On August 19, 1993, the Orthopedic and Rehabilitation Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On April 20, 1994, CDRH approved the application by a letter to the applicant from the Acting Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and